

## REMARKS/ARGUMENTS

Claims 1, 3-4, 7-8, 10, 12, 14-29, and 36-39 remain in this application. Claims 7 and 36-39 have been amended.

The Examiner has acknowledged that claims 1, 3-4, 8-12, 14-15, 17, 19, 21, 23, 25, and 27 are directed to allowable subject matter.

Claim 7 has been amended to replace the phrase “has transcriptional regulatory activity” with --is a promoter--. Support for this amendment can be found at page 13, lines 9-11; page 13, lines 18-22; and page 20, line 1, of the specification.

Claims 36-39 have been amended to replace the phrase “at least 19” with --20--. Support for this amendment can be found on page 33, line 10, to page 34, line 4; page 10, line 16, to page 12, line 11, with reference to Figures 6-8; page 22, lines 4-9 and 15-20; Example 2; page 32, lines 3-20; page 28, lines 1-5, as well as with reference to Figure 1, which indicates the primers used; Figure 5, which specifies the region for differentiation between *EpEp* and *epep* genotypes; and SEQ ID NO:2 of the specification. Please see below for additional discussion of support for the claim amendments.

### Rejection for New Matter

Claims 36-39 are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the written description requirement. In the Advisory Action dated January 16, 2006, the Examiner alleged that “at least 19/20 contiguous nucleotides” of nucleotides 1524-1610 of SEQ ID NO:2 or its equivalent is not adequately described in the application and that this claim amendment constitutes new matter. Applicant respectfully disagrees with the Examiner’s rejection.

Applicant notes that claims 36-39 have been amended to specify that the nucleotide sequence used to differentiate between *EpEp* and *epep* plants comprises 20 nucleotides from nucleotides 1524-1610 of SEQ ID NO:2.

Claims 36-39 relate to methods that may be used to differentiate *EpEp* and *epep* genotypes that involve sequence comparisons between the genotypes. The use of sequences to distinguish *EpEp* and *epep* genotypes is described in several places within the specification, for example on page 10, line 16, to page 12, line 11, with reference to Figures 6-8; page 22, lines 4-9 and 15-20; Example 2; page 32, lines 3-20; and page 33, line 10, to page 34, line 4, of the specification. On page 28, lines 1-5, and Figure 1 of the specification, there are provided examples of nucleotide sequences that may be used to distinguish between the *EpEp* and *epep* genotypes.

An example of a nucleotide sequence that resides within nucleotides 1524-1610 of SEQ ID NO:2 (the 87 base pair region that differentiates the *EpEp* and *epep* genotypes) is “prx9+,” a 20 contiguous nucleotide sequence comprising the nucleotides ATGCATGCAGGTTTTTCAGT (see page 28, line 3). The sequence prx9+ is an example of a sequence that may be used to determine whether or not an 87 base pair sequence is present or absent within a sample (see page 33, line 10, to page 34, line 4). The use of prx9+ to identify *EpEp* and *epep* genotypes is exemplified in Figures 6-8, and described on page 22, lines 4-20, and page 33, line 10, to page 34, line 4, of the specification. Other 20-mer primers are also used in the method of the present invention for example, see prx2+, prx6-, prx10-, and prx12+ (page 28, lines 1-2 and 4-5).

It would be evident to one of skill in the art that other sequences within the 87 base pair region identified (nucleotides 1524-1610 of SEQ ID NO:2) can be used to differentiate the *EpEp* and *epep* genotypes using the methods disclosed. More particularly, a person of skill in the art would know that primers or nucleotide sequences comprising 20 contiguous nucleotides within the 87 base pair region could be used in the context of the claimed methods.

Applicant submits that a person of skill in the art would clearly see that the “primer comprising 20 contiguous nucleotides selected from nucleotides 1524-1610 of SEQ ID NO:2” is supported by the original disclosure and does not add new matter. When defining a primer within the region of nucleotides 1524-1610 of SEQ ID NO:2, the 20 nucleotides of the primer must necessarily be contiguous within the that region. Furthermore, although the primer has not been

defined as comprising “20 contiguous nucleotides,” the number of nucleotides in the disclosed primers (for example, prx2+, prx6-, prx9+, prx10-, and prx12+) may be readily determined. Therefore, Applicant submits that the phrase “20 contiguous nucleotides selected from nucleotides 1524-1610 of SEQ ID NO:2” is not an addition of new matter, but rather it is inherent within the teaching of the present application.

Applicant requests withdrawal of the rejection of claims 36-39 under 35 U.S.C. 112.

### **Rejection for Lack of Scope of Enablement**

Claims 7, 16, 18, 20, 22, 24, 26, and 28-29 are rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the enablement requirement. The Examiner alleged in the Advisory Action dated January 16, 2006 that the rejection is a scope of enablement rejection, and that the sequences obtained from hybridization would not be identical to the probe sequence. Further, the Examiner contends that it would require undue experimentation to find transcriptional activity in hybridizing sequences. Applicant respectfully disagrees with this rejection.

Amended claim 7 is directed to an isolated DNA molecule comprising a nucleotide sequence that hybridizes to nucleotides 1-1532 of SEQ ID NO:2 or a complement thereof under specifically defined conditions, and that the DNA molecule exhibits a defined utility, in that it is a promoter. Applicant further notes that the claimed sequence is novel and unobvious in view of the prior art, the subject matter of the claim is supported by at least one sequence within the scope of the claimed genus, and that there has been a reduction to practice of the disclosed species. Applicant therefore submits that the scope of claim 7 is properly enabled as one of skill in the art may use the disclosed sequence and readily identify sequences that hybridize under stringent conditions and that exhibit promoter activity.

In support of this argument, Applicant notes with reference to pages 36-37 of “Example 9: Hybridization,” of the “Synopsis of Application of Written Description Guidelines” (January 16, 2003; [www.uspto.gov/web/menu/written.pdf](http://www.uspto.gov/web/menu/written.pdf)), that for a sequence that is novel and unobvious in

view of the prior art, where a single species is disclosed that is within the scope of the claimed genus, and where there is reduction to practice of the disclosed species, it is stated that:

“...a person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridisation conditions set forth in the claim yield structurally similar DNAs. Thus a representative number of species is disclosed, since highly stringent hybridisation conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are required to determine the applicant was in possession of the claimed invention.

**Conclusion:** The claimed invention is adequately described.”

Claims of a scope similar to that of claim 7, and with the same written description, are routinely allowed by the Patent & Trademark Office.

Applicant submits that a person of skill in the art would be readily able to identify a DNA molecule that hybridizes to nucleotides 1-1532 of SEQ ID NO:2 or its complement under the hybridisation conditions defined in claim 7. Furthermore, as the sequence defined in claim 7 is free of any cited art, and as the sequence is defined in combination with the function of the sequence (transcriptional regulatory activity), Applicant submits that the scope of the claim is adequately described.

With respect to the Examiner’s assertion of undue experimentation, Applicant submits that any skilled technician would be amply familiar with methods of assessing whether a DNA molecule is a promoter. For example, the specification refers provides an example of a protocol for analysing the regulatory activity of a DNA molecule (see page 21, lines 8-12). Therefore, it would be a matter of routine experimentation for a skilled person to determine whether the DNA molecule that hybridises to the nucleotides 1-1532 of SEQ ID NO:2 or its complement and to determine if it is a promoter.

With respect to the Examiner’s contention that the hybridizing molecules may not be identical to the probe sequence, and that a single mutation, substitution, or mismatch of the sequence would abolish any activity of a nucleic acid molecule, Applicant notes the following:

- claim 7 is directed to a sequence that is a promoter and not to a probe;
- a sequence that hybridises to the sequence defined in claim 7 may not be identical to SEQ ID NO:2, however, a sequence that hybridises under stringent conditions and that is a promoter is within the scope of the claim and that a person of skill in the art would recognize be able to make such a determination;
- claim 7 does not include sequences that are not promoters. Therefore, sequences that differ by even a single mutation, substitution, or mismatch of the sequence that do not have promoter activity do not fall within the scope of claim 7. Only hybridizing sequences that are promoters are included in the scope of claim 7.

Applicant therefore submits that the subject matter of claim 7 and claims 16, 18, 20, 22, 24, 26, and 28-29 dependent thereon, are adequately defined and enabled by the present specification, and it would not require any undue experimentation by a person of skill in the art to practice the claimed invention.

Applicant requests withdrawal of the rejection of claims 7, 16, 18, 20, 22, 24, 26, and 28-29 under 35 U.S.C. 112.

It is respectfully submitted that the above-identified application is in condition for allowance and favourable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact the Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted

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